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UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

ETHICON, INC. and INBAE YOON, M.D., *Plaintiffs,*	:	
-against-	:	Civil Action No. B 89-386 (RNC)
UNITED STATES SURGICAL CORPORATION, *Defendant,*	:	August 22, 1997
-and-	:	
YOUNG JAE CHOI, *Intervenor-Defendant.*	:	

ETHICON'S MEMORANDUM OF LAW IN OPPOSITION TO USSC'S MOTION FOR SUMMARY JUDGMENT STRIKING ETHICON'S AFFIRMATIVE DEFENSE OF INEQUITABLE CONDUCT

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I. THE STANDARD FOR INEQUITABLE CONDUCT

The standard of proof for inequitable conduct is intentionally set high, but in that regard it parallels the high standard of disclosure placed on applicants in the Patent Office. Applicants are intentionally held to a rigorous obligation of candor and, when they fall short, the Federal Circuit has not hesitated to declare unenforceable patents obtained by deceptive conduct. *Critikon, Inc. v. Becton-Dickinson Vascular Access, Inc.*, No. 95-1322 (Fed. Cir. Aug. 12, 1997) at p. 4 (attached to the Pippert Declaration as Exhibit 45); *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993).

Indeed, the doctrine rendering patents unenforceable if obtained by inequitable conduct is essential to protect the integrity of the patent system. The patent examiner deals with the applicant *ex parte*. He has limited resources and no ability to engage in independent investigation. Accordingly, the examiner must depend upon full and complete disclosure from the applicant. As the predecessor to the Federal Circuit, the Court of Customs and Patent Appeals, explained years ago in language that has been repeatedly endorsed over time:

> The ex parte prosecution and examination of a patent application must not be considered as an adversary proceeding and should not be limited to the standards required in inter partes proceedings. With the seemingly ever-increasing number of applications before it, the Patent Office has a tremendous burden. While being a fact-finding as well as an adjudicatory agency, it is necessarily limited in the time permitted to ascertain the facts necessary to adjudge the patentable merits of each application. In addition, it

> has no testing facilities of its own. Clearly it must rely on applicants for many of the facts upon which its decisions are based. The highest standards of honesty and candor on the part of applicants in presenting such facts to the office are thus necessary elements in a working patent system. We would go so far as to say they are essential.

Norton v. Curtiss, 433 F.2d 779, 793-94 (CCPA 1970)

The duty of candor is set forth by regulation, 37 C.F.R. § 1.56, and it is regularly emphasized — and enforced — by the courts. Just within the past two weeks the Federal Circuit has again reiterated this fundamental obligation of the patentee: "It is axiomatic that '[c]lose cases should be resolved by disclosure, not unilaterally by the applicant.'" *Critikon, Inc. v. Becton-Dickinson Vascular Access, Inc.,* at p. 8 (Pippert Decl. Ex. 45), *quoting LaBounty Mfg., Inc. v. United States Int'l Trade Commission,* 958 F.2d at 1066, 1076 (Fed. Cir. 1992).

Inequitable conduct must be proved by clear and convincing evidence. Proof of two elements is required: materiality and intent to deceive.

> The doctrine of inequitable conduct requires a trial court to undertake a two-step analysis. The trial court must discern whether the withheld references satisfy a threshold level of materiality. The court must also determine whether the applicant's conduct satisfies a threshold showing of intent to mislead.

Halliburton Co. v. Schlumberger Technology Corp., 925 F.2d at 1435, 1439 (Fed. Cir. 1991); *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.,* 863 F.2d 867, 872 (Fed. Cir. 1988). Once these threshold showings have been made, the court must then balance the elements to determine whether inequitable conduct occurred. "The more

material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." *Critikon, Inc. v. Becton-Dickinson Vascular Access, Inc.*, at p. 5 (Pippert Decl. Exhibit 45); *Akzo v. the United States Int'l Trade Commission*, 808 F.2d 1471, 1478 (Fed. Cir. 1986). In this regard, the Court will scrutinize the conduct of the applicant, the assignee and the attorneys. *Molins PLC v. Textron*, 48 F.3rd 1172, 1178 note 6 (Fed. Cir. 1995).

"Direct evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable conduct, but intent may be inferred from the surrounding circumstances." *Critikon, Inc. v. Becton-Dickinson Vascular Access, Inc.* at p. 6 (Pippert Decl. Ex. 45).

To overcome the inference of intentional deception, U.S. Surgical's witnesses must come forward with a "good faith explanation" sufficient to render the circumstances innocent. A "mere denial . . . will not suffice." *Critikon, Inc. v. Becton-Dickinson Vascular Access, Inc.* at p. 8 (Pippert Decl. Ex. 45). *Cf. Paragon,* 984 F.2d at 1191 (declaration of lack of intent to mislead insufficient to create a genuine issue of fact to avoid summary judgment).